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Field Service Procedure

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Installation of MRI System Filter Box and Power Supply/Charger, with Imaging Test Protocol

Installation of MRI System Filter Box and Power Supply/Charger, with Imaging Test Protocol

Installation Procedure

General Warnings and Cautions that apply to this Service Procedure:

- **WARNING:** Any person involved with the setup, operation, or maintenance of the Narkomed MRI anesthesia system must be thoroughly familiar with the instruction manual for this product.
- **WARNING:** Do not place any object on this machine unless it is specifically labeled to be used in an MRI scanning room and on the Narkomed MRI anesthesia system. Objects placed on this machine that are not designed for use with this anesthesia system may be strongly attracted to the magnet and may cause serious injury or death when the machine is used in an MRI scanning room.
- **WARNING:** Always lock the casters after this anesthesia machine has been positioned in the MRI scanner room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the anesthesia machine if the casters are unlocked.
- **WARNING:** The power supply charger assembly must not be taken into the magnet room. Damage to the equipment, MRI system, or personal injury could result.
- **WARNING**: This anesthesia machine has been tested only with magnets having field strengths of up to 3 tesla. Moving the machine near higher strength magnets could result in machine malfunction or unmanageable attractive forces that could lead to serious injury or death.
- **WARNING:** Use only nonmagnetic (aluminum) E-cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.
- **CAUTION:** When moving the machine, be sure to set the absorber to its lowest position on the absorber pole. To avoid personal injury or damage to the unit, do not use the absorber pole to push or pull the machine. It is recommended that two people move the machine to aid in maneuverability on inclines, around corners, and over raised thresholds.

Installing the Power Supply Filter:

The power supply filter is furnished as a double box assembly that must be reassembled in a through-the-wall arrangement, in the MRI room access panel as shown in Figure 1 and Figure 2.

WARNING: Do not bring any ferromagnetic tools or equipment into the scanning room. Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

- 1. Remove any shroud covers to expose the access panel on both the inside and the outside of the MRI room. See illustration on next page.
- 2. Select a suitable location for the filter box on the MRI room access panel. The average access panel has removable plates. A suitable location would be an unused plate on the access panel, or a plate that has sufficient room to easily mount both sides of the filter without disturbing other installed equipment.
- 3. Remove the selected plate from the access panel and find a suitable place for drilling. Carefully mark and drill two ½ inch holes in the removed plate according to the dimensions given in Detail A in Figure 2. Remove any burrs from both sides of the plate.
- 4. Remove the box covers and the cover screws (located in a bag) from the filter assembly, and disconnect the red and black wires from the inside box filter terminals. DO NOT disturb the ground stud wiring (not shown).
- 5. Remove the ½-28 nuts and lock washers from the filter bushings, and separate the inside box from the filter box.

6. Re-assemble the boxes as shown in the illustration - with the filter box on the outside of the access panel, and the inside box on the MRI room side of the access panel. Secure the assembly with the lock washers and ½-28 nuts on the filter bushings.

NOTE: The filters and each side of the filter box must be mounted <u>flush</u> on the removable plate to ensure RF integrity.

- 7. Reconnect the red and black wires to the inside box filter terminals.
- 8. Verify that the red wire in the inside box is connected to the same filter element as the red wire in the outside filter box.
- 9. Install the covers on both boxes using the hardware found inside the box covers.
- 10. From outside the MRI room, put the cable with the female connector (from the inside filter box) through the access panel where the plate was removed, and reinstall the assembled filter box and plate back on the access panel where the plate was previously removed.

NOTE: All hardware securing the plate to the access panel must be tightly secured.

11. Reinstall any shroud cover inside the MRI room that was previously removed. Ensure that the DC power cable is accessible for connection to the machine's cable. See Figure 3.

TYPICAL MRI ROOM ACCESS PANEL (SHOWN WITHOUT SHROUD COVER)

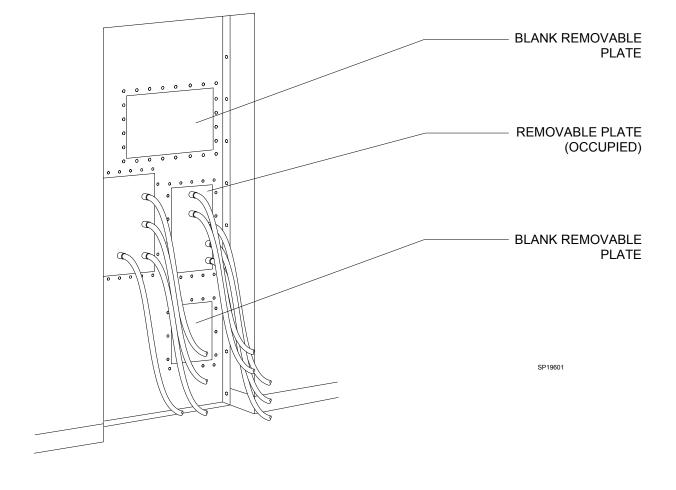


FIGURE 1. MRI Room Access Panel

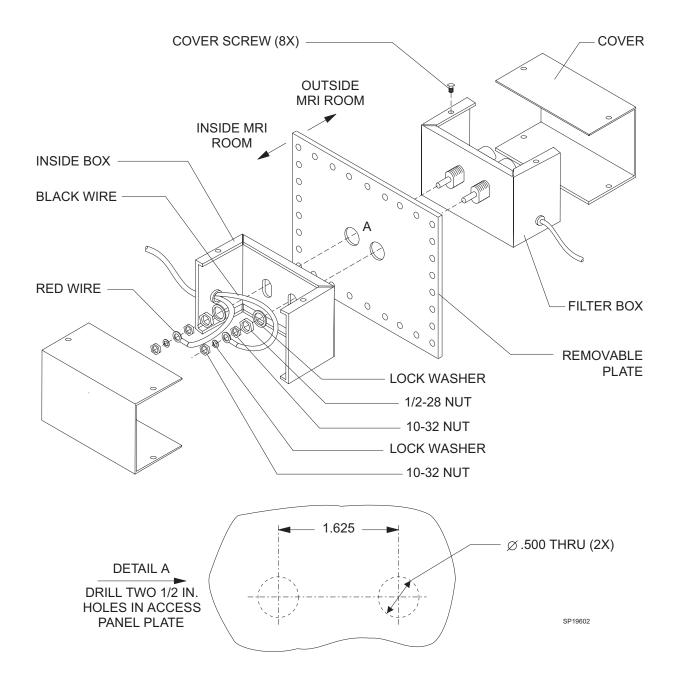


FIGURE 2. Filter Box Assembly Details

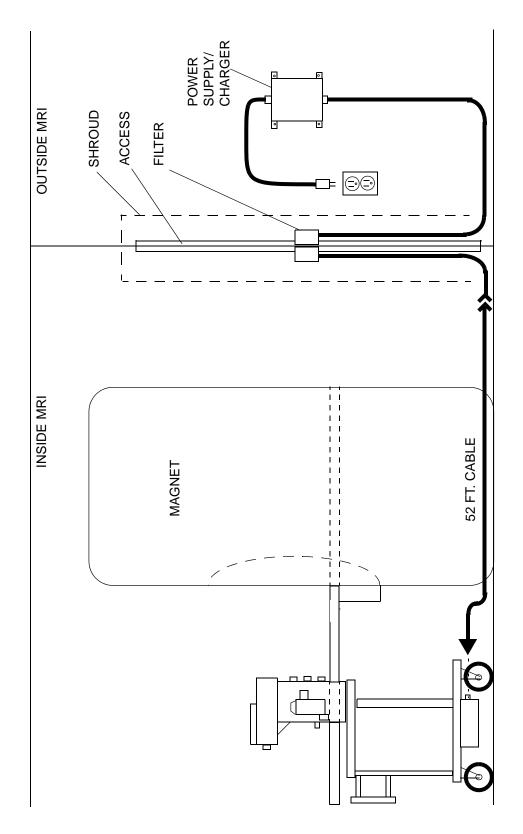


FIGURE 3. MRI Installation Profile

Installing the Power Supply/Charger:

Select a suitable location for the power supply on the outside wall of the MRI room. The power supply should be located in the vicinity of the previously installed filter box, at a distance that will accommodate the input cable attached to the filter box, and to the nearest AC receptacle.

Warning: The power supply charger assembly must not be taken into the magnet room. Damage to the equipment, MRI system, or personal injury could result.

Warning: The power supply charger must not reside in an area where field strength is greater than 50 gauss.

The power supply charger has mounting holes suitable for #8 diameter screws. The type of fastener used will depend upon the wall material at your location. Coordinate mounting of the power supply charger with the MRI or Biomed technician at a location that considers the available cable length from the filter box to the nearest AC receptacle.

- 1. Hold the power supply charger in place and carefully mark the four mounting hole locations as shown in the illustration.
- 2. Attach the power supply charger to the wall with four screws. Minimum recommended length is ¼ in.

Connecting to Electrical Power:

- 1. Verify that the SYSTEM POWER switch on the front of the anesthesia machine is set to STANDBY.
- 2. Disconnect the female end of the 52 ft cable attached at the rear of the machine.
- 3. Attach the cable from the filter box to the power supply charger.
- 4. Connect the AC power cord to the power supply charger, and the opposite end to an AC receptacle.
- 5. Connect the cable from the inside box of the power supply filter to the end of the 52 ft cable (see Figure 4).
- 6. Measure the voltage between Pin 1 referenced to Pin 2 at the connector on the 52 ft cable (see illustration on next page). The voltage should be between +13.6 VDC and +14.5 VDC.
- 7. Connect the female end of the 52 ft DC power cord to the power inlet connector located at the rear of the machine.
- 8. Reinstall any shroud cover that was previously removed.

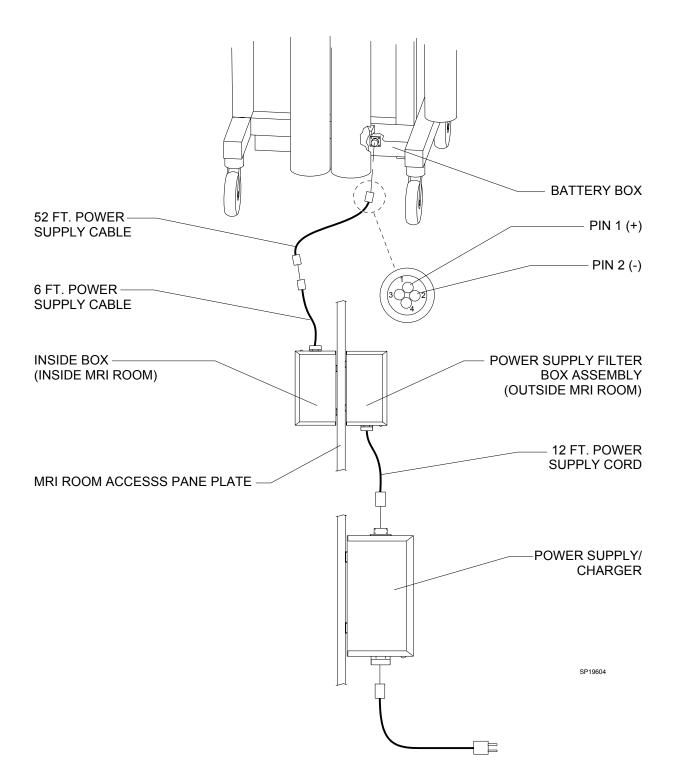


FIGURE 4. Electrical Connections

Setup:

Three (3) procedures must be performed before the Narkomed MRI is put into service in the MRI scanning room:

- Power supply filter box installed on MRI room access panel
- Narkomed MRI PMC completed (pass all conditions)
- Imaging Test Protocol (pass all scans)

The purpose of these tests is to verify that the Narkomed MRI does not interfere with the diagnostic quality of the MR images.

NOTE: If any of these procedures are not successfully completed during the initial setup of the machine, do not remove label "Warning Do Not Use or Place..." (Part # 4115245) from the flowmeter shield. Review the status of the setup and installation procedure and the recommendations, with the customer. Also, complete a "WARNING THIS MACHINE IS NOT CERTIFIED" label (P/N 4114857) and place it at a prominent location on the right side of the machine. Ensure that the "General Comments" on the PMC form and "Executive Summary" fields indicate the condition and reason why the machine is not certified. Some examples are:

- P/S filter not installed: "Power supply filter not installed at time of machine setup"
- Incomplete ITP: "ITP incomplete at time of machine setup"
- Failed ITP: "The Imaging Test Protocol does not indicate a pass condition"

Imaging Test Protocol (ITP) Overview:

An ITP is required to complete the installation and approximately 30 minutes of magnet time is needed. The ITP consists of five (5) scans, described as follows:

Type of scans:

4 scans, 2-Dimensional Spin Echo (2DSE), 1 scan, customer choice

(Refer to scan sequence details on following pages.)

- The first scan is performed after the filter box is installed on the access panel, with the anesthesia machine outside the MRI room and with a head coil/phantom. This is a base line scan to verify the room integrity.
- 2. The next scan, again with the **head coil** is performed with the machine in the MRI room in a position typical of where it is used clinically.
- 3. The third scan is a base line scan with a **body coil**, with the machine outside the MRI room.
- 4. The fourth scan, again with the **body coil**, and with the machine in the MRI room in a position typical of where it is used clinically.
- 5. The fifth scan shall be any type of clinical scan chosen by the MRI technician. The scan shall be performed using any type of phantom coil, with the machine in the MRI room in a position typical of where it is used clinically.

The TSR shall record the results of these imaging tests on the ITP form and checklist (see following pages), as determined by the hospital MRI technician.

Fill out a copy of the ITP checklist and Imaging Test Protocol form. Mail these to: Technical Service Department

> Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969-9977

Scan Sequence Details:

<u>Scan 1</u>: Two dimensional Spin Echo (2DSE), baseline scan with **head coil**, machine outside scanner room.

Machine set-up for Scans 1 and 3:

- Disconnect the power cable from the rear of the Narkomed MRI machine. Remove the MRI machine from the scanner room
- Perform the first scan and verify with the MRI technicial that the image system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form shown at the end of this procedure.

Note: Recheck the installed Narkomed MRI system for obvious installation errors if the tests do not pass.

<u>Scan 2</u>: Two dimensional Spin Echo (2DSE), **head coil**, machine in the scanner room.

Return the Narkomed MRI to the scanner room, to a position typical of where the machine would be used clinically. Lock the casters and connect the 52-ft. power cable to the rear of the Narkomed MRI machine.

Machine set-up for Scans 2, 4 and 5:

- Turn the System Power switch to ON and allow monitor and ventilator to complete the power-up self-test and lamp test. Verify all tests are completed successfully.
- Verify that the AC Power Fail LED on the alarm channel is not lighted.

The following steps do not have to be performed with a test lung:

- Perform O2 cell calibration. Place the sensor housing on machine table top.
 Verify O2 calibration was completed successfully.
- Set the ventilator to 10 BPM, I:E ratio of 1:1, and turn ventilator ON.
- Perform the second scan and verify with the MRI technician that the imaging system is performing to its specifications with acceptable quality. Record the Service Protocol and results on the ITP form.

Scan 3: Two Dimensional Spin Echo (2DSE), baseline scan with **body coil**, machine outside scanner room.

Refer to Machine set-up for Scans 1 and 3.

 Perform the third scan and verify with the MRI technician that the image system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form shown at the end of this procedure.

<u>Scan 4</u>: Two Dimensional Spin Echo (2DSE), **body coil**, machine in the scanner room.

Return the Narkomed MRI to the scanner room, to a position typical of where the machine would be used clinically. Lock the casters and connect the 52-ft. power cable to the rear of the Narkomed MRI machine.

Refer to Machine set-up for Scans 2, 4 and 5.

 Perform the fourth scan and verify with the MRI technician that the image system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form shown at the end of this procedure.

<u>Scan 5</u>: Customer choice of clinical scan, choice of coil (body, head, extremity), machine in scanner room.

Machine location and setup remains same as for Scan 4.

Refer to Machine set-up for Scans 2, 4 and 5.

• Perform the fifth scan and verify with the MRI technician that the image system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form shown at the end of this procedure.

Fill out a copy of the following ITP checklist and Imaging Test Protocol form. Mail these to:

Technical Service Department Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969-9977

Telford, PA 18969-9977

SETUP AND INSTALLATION IMAGING TEST PROTOCOL

Hospital
Narkomed MRI Serial #
Magnet Center or Resonant Frequency: MHz
Service Protocol Name or Sequence Used (Obtain hospital MRI operator):
Scan 1:
Scan 2:
Scan 3:
Scan 4:
Scan 5:
COMMENTS ON IMAGE QUALITY
Scan 1:
Scan 2:
Scan 3:
Scan 4:
Scan 5:
All Imaging Tests Passed?YesNo
Installation type (circle one): New machine installation Monitor upgrade Repair
MRI Service Representative or hospital MRI operator (print):
Phone Number:
NAD Service Representative (sign)
Date:
Mail copies of this report and the ITP Checklist to:
Technical Service Department Draeger Medical, Inc. 3122 Commerce Drive

NM MRI IMAGING TEST PROTOCOL (ITP) CHECKLIST

1.	Verify that each side of the filter box is mounted flush with the penetration panel.		
2.	Verify that the voltage measured at the 52' cable connector, that joins the connector on the back of the NM MRI machine, is between +13.6 VDC and +14.5 VDC when measured at Pin 1, referenced to Pin 2.		
3.	Verify that the power supply charger is located outside of the MRI room.		
4.	Verify with the MRI technician that the MRI system at the site is fully functional.		
5.	Have the MRI technician perform a baseline scan using the head phantom.		
6.	Verify with the MRI technician that the NM MRI machine works in conjunction with the MRI system using the head phantom.		
7.	Have the MRI technician perform a baseline scan using the body phantom.		
8.	Verify with the MRI technician that the NM MRI machine works in conjunction with the MRI system using the body phantom.		
9.	Have the MRI technician run any additional scans to confirm that the MRI system is working properly in conjunction with the NM MRI machine.		
10.	Fill out the ITP report and attach this checklist to the ITP. Remember to include the name of the hospital, and to sign and date the report before sending it to NAD.		
Hospital			
Narkomed MRI Serial #			
NAD Service Representative (sign)			
D-	Detail		

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